

# The effect of transfusion on cerebral oxygenation in traumatic brain injury

**Submission date**  
08/09/2005







**Recruitment status**  
No longer recruiting

**Registration date**  
06/10/2005

**Overall study status**  
Completed

**Last Edited**  
03/03/2009

**Condition category**  
Injury, Occupational Diseases, Poisoning

-  Retrospectively registered
-  Protocol not yet added
-  SAP not yet added
-  Results added
-  Raw data not yet added
-  Study completed

## Plain English Summary

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Arun Gupta

### Contact details

Department of Anaesthesia  
Box 93  
Cambridge  
United Kingdom  
CB2 2QQ  
akg01@globalnet.co.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

LREC 02/191

## Study information

**Scientific Title**

The effect of transfusion on cerebral oxygenation in traumatic brain injury: a randomised controlled trial

**Study hypothesis**

Blood transfusion does not affect brain oxygenation in traumatic brain injury.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Condition**

Traumatic brain injury

**Interventions**

Blood transfusion - the patients are randomised to 3 different transfusion triggers

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Brain tissue oxygen partial pressure.

**Secondary outcome measures**

1. Jugular venous saturation
2. Lactate/pyruvate ratio
3. Neurological outcome
4. Cerebral haemodynamics

**Overall study start date**

01/07/2002

**Overall study end date**

01/12/2005

## Eligibility

**Participant inclusion criteria**

1. Greater than 16 years of age
2. Severe traumatic brain injury (i.e. traumatic brain injury resulting in a resuscitated Glasgow coma score of less than or equal to 8, resulting in intracranial hypertension (greater than 20 mmHg for greater than 10 minutes), or requiring neurosurgical intervention
3. Informed assent from the next of kin

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Participant exclusion criteria**

1. Active haemorrhage
2. Active coronary ischaemia as judged by dynamic electrocardiogram (ECG) changes or positive troponin levels not due to myocardial contusion
3. Inability to place cerebral oxygenation monitors
4. Failure to fall below allocated transfusion threshold during intracranial pressure (ICP) monitoring

**Recruitment start date**

01/07/2002

**Recruitment end date**

01/12/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Department of Anaesthesia**  
Cambridge  
United Kingdom  
CB2 2QQ

## **Sponsor information**

### **Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

### **Sponsor details**

Addenbrooke's Hospital  
Hills Road  
Cambridge  
England  
United Kingdom  
CB2 2QQ  
jn254@cam.ac.uk

### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.cuh.org.uk/>

### **ROR**

<https://ror.org/04v54gj93>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Association of Anaesthetists of Great Britain and Ireland (UK)

### **Funder Name**

Intensive Care Society (UK)

### **Alternative Name(s)**

ICS

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

**Funder Name**

Codman (Johnson & Johnson) (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2009		Yes	No